Center For Drug Evaluation and Research
List of Guidance Documents

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M4 - The CTD -- General Questions and Answers (Revised) (I)	12/22/2004

M4 - The CTD - Quality Questions and Answers/Location Issues (I)	6/9/2004
M4 - The CTD -- Safety Questions and Answers (I)	2/4/2003

ICH - Quality	**Issued Date**
Q1A(R2) - Stability Testing of New Drug Substances and Products (I)	11/21/2003
Q1B - Photostability Testing of New Drug Substances and Products (I)	5/16/1997
Q1C - Stability Testing for New Dosage Forms (I)	5/9/1997
Q1D - Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products (I)	1/16/2003
Q1E - Evaluation of Stability Data (I)	6/8/2004
Q2A - Text on Validation of Analytical Procedures (I)	3/1/1995
Q2B - Validation of Analytical Procedures: Methodology (I)	5/9/1997
Q3A(R) - Impurities in New Drug Substances (I)	2/11/2003
Q3B(R) - Impurities in New Drug Products (I)	7/31/2006
Q3C - Impurities: Residual Solvents (I)	12/24/1997
Q3C - Tables and Lists (Revised) Recommendations for Methylpyrrolidone and Tetrahydrofuran (I)	11/13/2003
Q5A - Viral Safety Evaluation of Biotechnology Products Derived From Cell Lines of Human or Animal Origin (I)	9/24/1998
Q5B - Quality of Biotechnology Products: Analysis of the Expression Construct in Cells Used for Production of r-DNA Derived Protein Products (I)	2/23/1996

Q5C - Quality of Biotechnological Products: Stability Testing of Biotechnology/Biological Products (I	7/10/1996
Q5D - Quality of Biotechnological/Biological Products: Derivation and Characterization of Cell Substrates Used for Production of Biotechnological/Biological Products (I)	9/21/1998
Q5E - Comparability of Biotechnological/Biological Products Subject to Changes in Their Manufacturing Process (I)	6/30/2005
Q6A - Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances (I)	12/29/2000
Q6B - Test Procedures and Acceptance Criteria for Biotechnological/Biological Products (I)	8/18/1999
Q7A - Good Manufacturing Practice for Active Pharmaceutical Ingredients (I)	9/25/2001
Q8 - Pharmaceutical Development (I)	5/22/2006
Q9 - Quality Risk Management (I)	6/2/2006

ICH - Safety	**Issued Date**
S1A - The Need for Long-Term Rodent Carcinogenicity Studies of Pharmaceuticals (I)	3/1/1996
S1B - Testing for Carcinogenicity in Pharmaceuticals (I)	2/23/1998
S1C - Dose Selection for Carcinogenicity Studies of Pharmaceuticals (I)	3/1/1995
S1C(R) - Dose Selection for Carcinogenicity Studies of Pharmaceuticals: Addendum on a Limit Dose and Related Notes (I)	12/4/1997
S2A - Specific Aspects of Regulatory Genotoxicity Tests for Pharmaceuticals (I)	4/24/1996
S2B - Genotoxicity: Standard Battery Testing (I)	11/21/1997
S3A - Toxicokinetics: The Assessment of Systemic Exposure in Toxicity Studies (I)	3/1/1995

S3B - Pharmacokinetics: Repeated Dose Tissue Distribution Studies (I)	3/1/1995
S4A - Duration of Chronic Toxicity Testing in Animals (Rodent and Nonrodent Toxicity Testing) (I)	6/25/1999
S5A - Detection of Toxicity to Reproduction for Medicinal Products (I)	9/22/1994
S5B - Detection of Toxicity to Reproduction for Medicinal Products: Addendum on Toxicity to Male Fertility (I)	4/5/1996
S6 - Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals (I)	11/18/1997
S7A - Safety Pharmacology Studies for Human Pharmaceuticals (I)	7/13/2001
S7B - Nonclinical Evaluation of the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals (I)	10/20/2005
S8 - Immunotoxicity Studies for Human Pharmaceuticals (I)	4/13/2006

ICH Draft - Efficacy	**Issued Date**
E12A Principles for Clinical Evaluation of New Antihypertensive Drugs (I)	8/9/2000
E2B(R) - Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports (I)	10/3/2005
E2D - Postapproval Safety Data Management: Definitions and Standards for Expedited Reporting (I)	9/15/2003

ICH Draft - Joint Safety/Efficacy (Multidisciplinary)	**Issued Date**
M5 - Data Elements and Standards for Drug Dictionaries (I)	9/6/2005
Submitting Marketing Applications According to the ICH/CTD Format; General Considerations (I)	9/5/2001

ICH Draft - Quality	**Issued Date**
Q4B: Regulatory Acceptance of Analytical Procedures and/or Acceptance Criteria (RAAPAC) (I)	8/8/2006

Q4B: RAAPAC - Annex 1: Residue on Ignition/Sulphated Ash General Chapter Analytical Procedures and/or Acceptance Criteria (APAC) (I)	8/8/2006

INDs	**Issued Date**
Content and Format of INDs for Phase 1 Studies of Drugs Including Well-Characterized, Therapeutic, Biotechnology-Derived Products (I)	10/4/2000

Industry Letters	**Issued Date**
A Revision in Sample Collection Under the Compliance Program Pertaining to Pre-Approval Inspections	7/15/1996
Certification Requirements for Debarred Individuals in Drug Applications	6/1/1990
Continuation of a series of letters communicating interim and informal generic drug policy and guidance. Availability of Policy and Procedure Guides, and further operational changes to the generic drug review program (I)	3/2/1998
Fifth of a series of letters providing informal notice about the Act, discussing the statutory mechanism by which ANDA applicants may make modifications in approved drugs where clinical data is required (I)	4/10/1987
Fourth of a series of letters providing informal notice to all affected parties about policy developments and interpretations regarding the Act. Three year exclusivity provisions of Title I (I)	10/31/1986
Implementation of the Drug Price Competition and Patent Term Restoration Act. Preliminary Guidance (I)	10/11/1984
Implementation Plan USP injection nomenclature (I)	10/2/1995
Instructions for Filing Supplements Under the Provisions of SUPAC-IR	4/11/1996
Seventh of a series of letters about the Act providing guidance on the "180-day exclusivity" provision of section 505(j)(4)(B)(iv) of the FD&C (I)	7/29/1988
Sixth of a series of informal notice letters about the Act discussing 3- and 5-year exclusivity provisions of sections 505(c)(3)(D) and 505(j)(4)(D) of the FD&C Act (I)	4/28/1988
Streamlining Initiatives	12/24/1996
Supplement to 10/11/84 letter about policies, procedures and implementation of the Act (Q & A format) (I)	11/16/1984

Third of a series of letters regarding the implementation of the Act (I)	5/1/1985
Year 2000 Letter from Dr. Janet Woodcock (I)	10/19/1998

Labeling	**Issued Date**
Adverse Reactions Section of Labeling for Human Prescription Drug and Biological Products; Content and Format (I)	1/24/2006
Barbiturate, Single Entity-Class Labeling	3/1/1981
Clinical Studies Section of Labeling for Human Prescription Drug and Biological Products; Content and Format (I)	1/24/2006
Content and Format for Geriatric Labeling (I)	10/5/2001
Hypoglycemic Oral Agents - Federal Register	4/1/1984
Labeling Over-the-Counter Human Drug Products; Updating Labeling In Reference Listed Drugs and Abbreviated New Drug Applications (I)	10/18/2002
Local Anesthetics - Class Labeling	9/1/1982

Labeling Draft	**Issued Date**
Labeling for Combined Oral Contraceptives (I)	3/5/2004
Labeling for Human Prescripstion Drug and Biological Products; Implementing the New Content and Format Requirements (I)	1/24/2006
Noncontraceptive Estrogen Drug Products for the Treatment of Vasomotor Symptoms and Vulvar and Vaginal Atrophy Symptoms — Recommended Prescribing Information for Health Care Providers and Patient Labeling (I)	11/16/2005
OTC Topical Drug Products for the Treatment of Vaginal Yeast Infections (Vulvovaginal Candidiasis) (I)	7/16/1998
Referencing Discontinued Labeling for Listed Drugs in Abbreviated New Drug Applications (I)	10/26/2000

Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products; Content and Format (I)	1/24/2006

OTC	**Issued Date**
Enforcement Policy on Marketing OTC Combination Products (CPG 71320.16) (I)	5/1/1984
General Guidelines for OTC Combination Products (I)	11/28/1978
Labeling OTC Human Drug Products -- Updating Labeling in ANDAs (I)	2/22/2001
Labeling OTC Human Drug Products Using a Column Format (I)	12/19/2000
Upgrading Category III Antiperspirants to Category I (43 FR 46728 - 46731) (I)	10/10/1978

OTC Draft	**Issued Date**
Labeling OTC Human Drug Products - Submitting Requests for Exemptions and Deferrals (I)	12/19/2000
Labeling Over-the-Counter Human Drug Products; Questions and Answers	1/13/2005
OTC Actual Use Studies	7/22/1994
OTC Nicotine Substitutes	3/1/1994
Small Business Entities on Labeling Over-the-Counter Human Drug Products (I)	12/9/2004
Time and Extent Applications (I)	2/10/2004

Pharmacology/Toxicology	**Issued Date**
Carcinogenicity Study Protocol Submissions (I)	5/23/2002
Estimating the Maximum Safe Starting Dose in Initial Clinical Trials for Therapeutics in Adult Healthy Volunteers (I)	7/22/2005

Exploratory IND Studies (I)	1/17/2006
Format and Content of the Nonclinical Pharmacology/ Toxicology Section of an Application (I)	2/1/1987
Immunotoxicology Evaluation of Investigational New Drugs (I)	11/1/2002
Nonclinical Pharmacology/Toxicology Department of Topical Drugs Intended to Prevent the Transmission of Sexually Transmitted Diseases (STD) and/or the Development of Drugs Intended to Act as Vaginal Contraceptives (I)	10/16/1996
Nonclinical Safety Evaluation of Drug or Biologic Combinations (I)	3/15/2006
Nonclinical Safety Evaluation of Pediatric Drug Products (I)	2/15/2006
Nonclinical Studies for the Safety Evaluation of Pharmaceutical Excipients	5/19/2005
Photosafety Testing (I)	5/7/2003
Recommended Approaches to Integration of Genetic Toxicology Study Results (I)	1/4/2006
Reference Guide for the Nonclinical Toxicity Studies of Antiviral Drugs Indicated for the Treatment of N/A Non-Life Threatening Disease: Evaluation of Drug Toxicity Prior to Phase I Clinical Studies (I)	2/1/1989
Single Dose Acute Toxicity Testing for Pharmaceuticals - Revised (I)	8/26/1996

Pharmacology/Toxicology Draft	**Issued Date**
Integration of Study Results to Access Concerns About Human Reproductive and Developmental Toxicities	11/13/2001
Nonclinical Evaluation of Late Radiation Toxicity of Therapeutic Radiopharmaceuticals (I)	6/20/2005
Safety Testing of Drug Metabolites	6/6/2005
Statistical Aspects of the Design, Analysis, and Interpretation of Chronic Rodent Carcinogenicity Studies of Pharmaceuticals (I)	5/8/2001

Procedural	Issued Date
180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act (I)	7/14/1998
Continuous Marketing Applications: Pilot 1--Reviewable Units for Fast Track Products Under the Prescription Drug User Fee Act of 1992 (I)	10/6/2003
Continuous Marketing Applications: Pilot 2--Scientific Feedback and Interactions During Development of Fast Track Products Under the Prescription Drug User Fee Act of 1992 (I)	10/6/2003
Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act	3/27/2000
Disclosure of Materials Provided to Advisory Committees in Connection with Open Advisory Committee Meetings Convened by the Center for Drug Evaluation and Research Beginning on January 1, 2000 (I)	11/30/1999
Drug Products Containing Ensulizole, Hypromellose, Meradimate, Octinoxate, and Octisalate - Labeling Enforcement Policy (I)	6/3/2003
Enforcement Policy During Implementation of Section 503A of the Federal Food, Drug, and Cosmetic Act (I)	11/23/1998
Fast Track Drug Development Programs: Designation, Development, and Application Review (I)	11/18/1998
FDA Export Certificate (I)	7/12/2004
Financial Disclosure by Clinical Investigators (I)	3/28/2001
Formal Dispute Resolution: Appeals Above the Division Level (I)	3/7/2000
Formal Meetings With Sponsors and Applicants For PDUFA Products (I)	3/7/2000
Implementation of Section 120 of the Food and Drug Administration Modernization Act of 1997-Elimination of Certain Labeling Requirements (I)	11/2/1998
Implementation of Section 126 of the FDA Modernization Act of 1997 - Elimination of Certain Labeling Requirements, (I)	7/21/1998
Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions (I)	3/18/2002

Levothyroxine Sodium Products - Enforcement of August 14, 2001, Compliance Date and Submission of New Applications (I)	7/13/2001
National Uniformity for Nonprescription Drugs Ingredient Labeling for OTC Drugs (I)	4/9/1998
Potassium Iodide (KI) in Radiation Emergencies - Questions and Answers (I)	12/23/2002
Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies (I)	12/11/2001
Potassium Iodide Tablets Shelf Life Extension for Federal Agencies and State and Local Governments (I)	3/8/2004
Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act - Revised (I)	10/1/1999
Refusal to File (I)	7/12/1993
Repeal of Section 507 of the Federal Food, Drug, and Cosmetic Act (I)	6/15/1998
Reports on the Status of Postmarketing Studies - Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997 (I)	2/16/2006
Special Protocol Assessment (I)	5/17/2002
Standards for the Prompt Review of Efficacy Supplements, Including Priority Efficacy Supplements (I)	5/15/1998
Submitting and Reviewing Complete Responses to Clinical Holds (Revised) (I)	10/26/2000
The Leveraging Handbook; an Agency Resource for Effective Collaborations - Guidance for FDA Staff (I)	6/19/2003
Useful Written Consumer Medication Information (CMI) (I)	7/18/2006
Women and Minorities Guidance Requirements	7/20/1998

Procedural Draft	Issued Date
Applications Covered by Section 505(b)(2) (I)	12/8/1999
Centralized IRB Review Proceedings in Multicenter Clinical Trials	3/23/2005
Clinical Trial Sponsors On the Establishment and Operation of Clinical Trial Data Monitoring Committees (I)	11/15/2001
Content and Format of New Drug Applications and Abbreviated New Drug Applications for Certain Positron Emission Tomography Drug Products (I)	3/10/2000
Disclosing Information Provided to Advisory Committees in Connection with Open Advisory Committee Meetings Related to the Testing or Approval of New Drugs and Convened by CDER, Beginning January 1, 2000 (I)	12/22/1999
Disclosure of Conflicts of Interest for Special Government Employees Participating in FDA Product Specific Advisory Committees	2/14/2002
Emergency Use Authroization of Medical Products (I)	7/5/2005
Fixed Dose Combination and Co-Packaged Drug Products for Treatment of HIV (I)	5/19/2004
Forms for Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution (I)	5/15/2001
Good Review Management Principles for PDUFA Products (I)	7/28/2003
How to Comply with the Pediatric Research Equity Act (I)	9/7/2005
Independent Consultants for Biotechnology Clinical Trial Protocols (I)	5/7/2003
Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions (I)	1/27/2004
Pharmacogenomic Data Submissions (I)	11/4/2003
Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines (I)	3/12/2001

Submitting Debarment Certification Statements (I)	10/2/1998
The Use of Clinical Holds Following Clinical Investigator Misconduct (I)	8/27/2002

Small Entity Compliance Guides	**Issued Date**
Sterility Requirements for Aqueous-Based Drug Products for Oral Inhalation (I)	11/7/2001

User Fee	**Issued Date**
Applicability of User Fees to (1) Applications Withdrawn Before Filing, or (2) Applications the Agency Has Refused to File and That Are Resubmitted or Filed Over Protest (Attachment F)	7/12/1993
Application, Product, and Establishment Fees: Common Issues and Their Resolution (Revised) (Attachment D) (I)	12/16/1994
Classifying Resubmissions in Response to Action Letters (I)	5/14/1998
Fees-Exceed-the-Costs Waivers Under the Prescription Drug User Fee Act (I)	8/25/1999
Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act (I)	11/21/2001
Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees (I)	1/3/2005

User Fee Draft	**Issued Date**
Document for Waivers of and Reductions in User Fees (Attachment G)	7/16/1993
User Fee Waivers for Fixed Dose Combination Products and Co-Packaged Human Immunodeficiency Virus Drugs for the President's Emergency Plan for Acquired Immunodeficiency Syndrome Relief (I)	4/18/2005